MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
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COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
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MARY K. WAKEFIELD, Ph.D.
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AGENDA ITEM:
Implementing the new Medicare drug benefit: Formulary issues - Cristina Boccuti, Joan Sokolovsky, Vivek Garg

MR. HACKBARTH: Next up is implementing the new Medicare drug benefit.

DR. SOKOLOVSKY: I would just like to provide a little context before Cristina and Vivek give us the presentation for this morning.

Now that Congress has enacted a Medicare prescription drug benefit to start in 2006, policymakers will have to make a long series of decisions on how the program will be implemented. These decisions will determine the cost, the efficiency and the quality of the benefit.

While legislators were debating the scope and structure of a prescription drug benefit, researchers conducted analyses that would enable them to better estimate the cost of the benefit. So work focused on things like estimating drug coverage of beneficiaries, figuring out expenditures for different categories of beneficiaries, and evaluating strategies adopted in the private sector to help control drug costs.

However, there's been much less research done to inform policymakers on the issues they're likely to encounter now as they implement a drug benefit. Yet issues like formulary systems that we'll hear about today, eligibility determination and enrollment and beneficiary education are complex issues that require careful planning based on solid information.

Large health plans report that implementation of a new drug benefit design typically requires lead time of at least one year. None of these plans would approach the size and complexity that will be involved in the implementation of the Medicare drug benefit.

In the next couple of months CMS intends to begin releasing a series of regulations related to implementation of the benefit. For a chapter in our June report we plan to focus on what we see as just some of the beginning key implementation issues to help prepare MedPAC to advise both Congress and CMS.

Next month we'll present the results from a series of structured interviews with present and former state Medicaid officials, directors of state pharmacy assistance programs, health plans and PBMs about what the key issues are for implementing the low-income drug benefit. Issues here include things like outreach and education, methods of eligibility determination and particularly the special problems relating to dual eligibles in long-term care facilities.

We also plan to present the results of a study on issues that arise when health plans sponsors switch from one

pharmacy benefit program to another. We've conducted a number of site visit, focus groups and structured interviews looking at best practices and also some of the problems that both plans and participants have experienced following the change.

Today Cristina and Vivek will present findings from our work on formularies. This work is designed to educate the policy community about formularies and lay out what we see as some of the key policy issues for Medicare around formulary development and utilization.

MS. BOCCUTI: To learn about formulary issues that policymakers are likely to encounter when implementing the new law we consulted available publications and interviewed experts and stakeholders on the topic, including representatives from health plans, PBMs, drug manufacturers, Medicare plans, the Veterans Health Administration, the Academy of Managed-Care Pharmacy, U.S. Pharmacopeia and consumer advocacy groups.

We have not yet completed all of our interviews and plan also to talk with physicians on their experiences with formularies.

Our presentation today and your mailing materials are designed to give you background information on formularies and begin to introduce some of the policy issues that policymakers and the commission may face in the future when formulary implementation regulations are being drafted.

The major questions we addressed are what are formularies and how do they operate? What does the new law say about formulary implementation? And what formulary related issues will Medicare and the Congress face when implementing the Medicare drug benefit?

Vivek is going to start with first bullet.

MR. GARG: A formulary is a continually updated list of drugs approved for coverage by a health care payer. A formulary is one component of a plan's overall formulary system which includes a set policies and procedures used to design, implement and update the formulary.

For example, there may be policies concerning the selection of drugs or how information about the formulary is communicated to physicians and beneficiaries.

Formularies can help educate physicians and enrollees on appropriate prescribing and utilization by identifying drugs proven to be a effective and safe for a plan's population. They can also help contain costs by directing use towards cost effective drugs and by giving plans the ability to negotiate for manufacturer rebates based on a market share a plan can shift towards a particular drug.

The majority of US workers with employer-sponsored drug coverage are in health plans that use formularies and formulary systems.

Formularies are composed of therapeutic classes which are the categories in which drugs are classified. There is no single way to classify drugs and they can be based on a mix of their therapeutic indications, the pharmacological mechanisms through which they act or their chemical structure. For example, antihypertensives lower blood pressure but include drugs with different pharmacological mechanisms such as those shown on the slide. And each drug which those groups has a distinct chemical structure that may affect its effectiveness and safety profile.

Most classification systems aim to place together drugs that produce similar therapeutic outcomes and have similar adverse reaction profiles. Plans we interviewed agreed that the classification system used can greatly affect a drug benefit as the therapeutic classes provide a framework for reviewing, selecting and inducing price competition among drugs. Many different classification systems exist and plans may create their own or adopt systems available commercially.

In addition, drugs can often be classified in more than one class. For example, beta-blockers are primarily used to treat hypertension by decreasing the heart's output of blood. However, some can and are used in the treatment of several types of heart conditions, migraines and anxiety. Although beta-blockers act through the same pharmacological mechanism, differences in their chemical structure alter their appropriate uses, effectiveness and safety profile. Based on these differences it would be possible to classify beta-blockers in one of several different therapeutic classes.

As these examples show, decisions about classification depend on the interpretations of medical experts in the formulary system which can differ significantly.

Formularies are developed and maintained by a body of experts known as a pharmacy and therapeutics committee, or P&T committee. All plans we interviewed relied on the input of a P&T committee in selecting drugs for the formulary.

The composition of P&T committees vary but generally consist of a majority of physicians from different specialties with some input by pharmacists. Our interviews show that physicians usually hold the majority vote on the committee, and in one case pharmacists were members of the committee but could not vote.

Some P&T committees vote on each drug being reviewed while others seek a consensus to determine drug coverage. Some plans emphasize the independence of their committee, drawing members from academia and expecting or requiring disclosure of conflicts of interest.

P&T committees determine whether a drug should be

placed on the formulary and in most cases what level of coverage it should have. To do so they review assembled information on the effectiveness and safety of available drugs. While effectiveness and safety are the primary factors for a drug's selection, our interviews revealed that cost becomes a factor at different points in the formulary process. Some plans take cost-effectiveness, price and pharmacoeconomic information into account while reviewing drugs. Others may first decide which drugs are therapeutically superior, equivalent or inferior and then negotiate and consider pricing among those determined to be equivalent in effectiveness and safety.

Most P&T committees meet at least yearly with many meeting quarterly. Meetings can vary from three to four hours to over the course of a few days. Some committees stagger their review of therapeutic classes across meetings, effectively canvassing the formulary over a year. Others may review the entire formulary once a year or set their agenda based on manufacturer contracts up for renewal. And most plans indicated that P&T committees reconsider drug selection as needed when new drugs or information becomes available.

Most formularies are variations of open or closed. In an open structure the plan covers all drugs in the therapeutic classes covered, whether listed on the formulary or not. Those that are listed are preferred by the plan for their quality or cost-effectiveness although there is no financial incentive for their use.

In a closed structure, only the listed drugs are covered and prescriptions can be shifted to these listed drugs to a greater degree.

Individual therapeutic classes may also be open or closed. For example, the statin class may be closed and restrict coverage to the listed drugs while the antihistamine class remains open with coverage of any available antihistamine. In practice, most formularies are a mix of open and closed classes and most plans do not cover particular classes of drugs, such as drugs proven to lack sufficient advocacy by the FDA, over-the-counter drugs, weight-loss, cosmetic or other lifestyle drugs.

Incentive-based formularies use cost-sharing differentials to direct use toward certain drugs on the formulary. The most popular form places drugs into three tiers and induces consumer price sensitivity while preserving access to a broader range of drugs. The first tier contains generic drugs which have the lowest level of cost-sharing. The second tier contains brand name drugs that are preferred by the plan and these have a middle level of cost-sharing. The third tier contains non-preferred brand name drugs with the highest level of cost-sharing.

In addition to cost-sharing differentials, formularies may contain other mechanisms to direct use. A

plan may require a drug to have prior authorization. In this case, the prescribing physician must provide evidence of the drug's medical necessity before the plan will cover it.

A plan may also establish step therapy for a certain condition. In this case certain first-line drugs must be tried and proved unsuccessful in treating the condition before other drugs are covered. Prior authorization and step therapy are often implemented when higher cost drugs are available that have limited value over lower cost drugs.

All plans we interviewed, though, had a medical exceptions process to cover drugs determined to be medically necessary by the physician subject to adequate support and approval by the plan.

Some plans stress the importance of such a mechanism to a well designed formulary. In most cases, claims were resolved in under 48 hours. One plan allowed pharmacists or physicians to prescribe a three day emergency supply of a drug if they believed it was medically necessary while the claim was being processed.

Now Cristina is going to continue.

MS. BOCCUTI: In implementing a formulary, the new law allows plans to establish their own classification system. However, it may not be designed to discourage enrollment of beneficiaries with high expected drug costs.

The law directs a model classification system to be developed by U.S. Pharmacopeia, which is an organization that sets and publishes quality standards for prescription drugs such as correct molecules and dosages. Plans are encouraged through safe harbor provisions to use USPs model, but again plans may develop their own classification system.

The specificity of a therapeutic class determines the mix of generic and brand name drugs available in a given class. The MMA requires that plans with formularies cover at least two drugs in each of its therapeutic categories. Plans may list a drug in more than one category. For example, we're recalling Vivek's diagram, plans may cover a beta blocker in two therapeutic categories, one for hypertension and the other for migraines.

Some of the plan and PBM representatives we interviewed indicated that if they use a formulary with narrow therapeutic classes, it minimizes their ability to contain costs for two reasons. First, narrow drug classes are more likely than broad classes to have no generic or moderately priced drug available.

Second, narrow drug classes are likely to reduce the degree of market competition within each class because fewer drugs are eligible for coverage in the class. This could consequently raise costs for plans, beneficiaries and the Medicare program if rebates and discounts are diminished.

Consumer advocates and representatives of the pharmaceutical industry expressed concerns that a broad classification system with too few classes could limit enrollees' access to medically necessary brand name drugs particularly those which best serve subpopulations who experience adverse side effects to lower cost drugs.

I'll just provide one example that compares narrow and broad classification structures which has received some attention in recent years and that is the classification of nonsteroidal anti-inflammatory drugs, NSAIDs, and Cox-II inhibitors. If a plan or PBMs classification system broke down NSAIDs into the subclass of Cox-II inhibitors, then under MMA the plan would have to cover at least two Cox-II inhibitors. At this time, only brand name Cox-II's are available.

If instead a plan's formulary did not classify Cox-II inhibitors separately from other NSAIDs, then the plan would not have to cover Cox-II's specifically and would likely choose to cover considerably less expensive NSAIDs within the broader NSAID category. In these cases, coverage for a Cox-II could occur through the medical exceptions process, potentially for people with gastrointestinal sensitivity.

So you can see the formularies are affected by the interplay between the plan's therapeutic class structure and the number of drugs covered per class. What we don't know yet is U.S. Pharmacopeia's model classification system and how plans, PBMS and physicians will respond to it.

In some cases, a beneficiary enrolled in a drug plan may need a non-formulary drug either because a formulary drug is not effective for them or because the formulary drug causes adverse side effects. The MMA requires the plan to have a process for enrollees to request coverage for non-formulary drugs or to change the drug's cost-sharing terra status. But first, a prescribing physician must determine that a non-formulary drug would be either more effective or cause less adverse side effects.

If beneficiaries are unable to obtain a non-formulary exception, they will have to pay high cost-sharing, up to the full retail cost of the drug. Moreover, their cost for purchasing non-formulary drugs will not count towards the out-of-pocket spending thresholds calculated for deductibles and stop loss in the Medicare drug benefit.

If non-formulary requests are denied, beneficiaries may appeal the decision in a process like that in the Medicare Advantage program. As Vivek mentioned, our interviews and research revealed the plans use a continuum of methods for reviewing non-formulary exceptions. Some are rather informal and ad hoc, say by telephone, while others require complex paperwork and proof that the beneficiary experienced either an adverse reaction to the drug or the drug failed as a treatment alternative.

Consumer advocates contend that if the process for obtaining non-formulary exceptions is too burdensome, then physicians may be less willing to participate in the non-formulary exceptions process which could affect beneficiaries' access.

Alternatively, plan and PBM representatives expressed concern that if non-formulary exceptions were too easy, the class control and drug management mechanisms built into the formulary would be greatly undermined.

As Vivek mentioned, formularies are frequently modified to reflect the introduction of new drugs in the market, updated clinical information and changes in market competition. The new law allows plans to change their formulary at any time during the plan year but they may only change their formulary's therapeutic classification categories at the beginning of a plan year.

Prior to removing or changing the tier status of a drug or the drug itself, plans must notify affected enrollees, physicians, pharmacies and pharmacists. Notifying enrollees about formulary changes is important because it can reduce those instances in which beneficiaries first learn at the pharmacy counter that their drug is no longer covered or has a higher cost-sharing. At the minimum, plans may post this information on an Internet web site. Consumer organizations comment that web site based communication can be useful but it's not sufficient to reach most beneficiaries.

A formulary change can have health and financial implications for beneficiaries because it requires that they either switch to a new drug or continue to use the original drug and pay for it themselves. Recent research published in the New England Journal of Medicine suggests that when copayments for drugs increase, some patients stop taking the drugs rather than switch to cheaper ones.

Some plan representatives we interviewed noted that for a limited number of drugs and illnesses grace periods or grandfathered exceptions for the removed drug may be granted automatically, such as for psychotropic drugs treating mental illness. However, when plans do not anticipate safety concerns, they are less likely to grant non-formulary exceptions based simply on a formulary change.

As you know, a large share of Medicare beneficiaries take multiple medications for chronic conditions. The new law does not stipulate that plans provide prospective enrollees with a list of covered drugs by name nor does it require the Secretary to disseminate formulary comparison information. However, upon enrollment and annually thereafter plans are required to provide information on how to request and obtain more specific formulary information. Note that it's common practice in commercial insurance to provide the actual formulary only to enrollees. This scenario means that beneficiaries cannot

select plans based on the drugs they cover.

Note that for beneficiaries taking multiple drugs, formulary comparisons may be quite a complex task and plans may well change their formulary after beneficiary enrollment.

As is current practice, MMA requires that plans have or contract with a P&T committee to develop and review their formularies. The law stipulates that the majority must be practicing physicians or pharmacists or both with at least two members of the committee considered independent experts. Representatives we interviewed were mixed on the issue of P&T committee member independence. Some stress the importance of total independence from the plan and from other intermediaries such as drug manufacturers. Others stated that including plan affiliated physicians and pharmacists on the P&T committee is important to formulary acceptance and compliance. In general, plans indicated that they would not have difficulties satisfying the P&T requirements in the new law.

Currently, two drugs are rarely tested against each other for effectiveness in treating the same condition which has led health insurers, providers, consumers and policymakers to advocate for independent head-to-head drug comparison studies. Single drug or placebo controlled studies are far more common.

Drug-to-drug trials could provide physicians and P&T committees with improved evidence on drug selection. The pharmaceutical industry contends that current research methods, which require considerable resources, are generally sufficient for physicians, plans and beneficiaries to make informed choices. The new law authorizes funding to the Agency for Health Care Research and Quality to conduct and support comparative research on health care items and services, which may include prescription drugs. As yet these funds have not been proposed in the President's budget nor by Congress and no amount was delineated specifically for prescription drug research.

MMA also notes potential for private partnerships in this regard. An alternative to the Congressional appropriations process could include funding a research institute through a percentage of drug sales. The independence of drug-to-drug comparison research is essential to its success. The study methodology would need to be transparent and subject to peer review to gain stakeholder respect.

In sum, conducting head-to-head studies would be very expensive and depending on the research design results could vary. So at issue, therefore, is who would conduct these tests and who would pay for them?

So in conclusion, we designed this presentation to give you background information on formularies and begin to introduce some of the formulary issues that policymakers and

the Commission may face in the future as implementation regulations are being drafted.

We welcome your comments and suggestions on the content, balance and usefulness of this information.

Thank you.

MR. FEEZOR: I would just like to compliment you on I think a great primer. I wish I'd had this at CalPERS when I was trying to get my board to understand as we were making a move from one PBM to another and we had just placed about 300,000 people from an open formulary to a closed. I'll give a couple of comments that I think we drew from that rather painful experience.

The first is, and Glenn, there were several states led by Kitzhaver and some of his staff were trying to put together an institute comparative drug studies. Do you know where that is?

The point is I would like to have us keep in front of us and in front of the decisionmakers here in Washington the need for at least a stimulus on the comparative effectiveness studies capacity, some sort of independent capacity.

A couple of comments growing out of our move at CalPERS to move from an open to a closed formulary at the same time we went with the three tier. think what is absolutely important is that, in fact, the formulary be posted. I know there is a selection issue there but I think individuals have to be able to try to make intelligent decisions, as confusing as it may be for people on multiples. So I think the open formulary is something that should be pursued.

If you allow the formulary to change at any time I think there are some real issues. I think the benefit -- particularly we found in our beneficiaries -- of saying that the formulary can only be changed once every benefit year in the case of commercial or perhaps quarterly or something like that. So it's more routine, it's sort of normal and there's an expectation that they can check.

Finding also that when there is a major change that having a transitional period, when we had 300,000 people that we changed PBM on, 50,000 of our folks who were on maintenance drugs were affected by that. Quite honestly, if I had known that, I would have been a little bit more reluctant to recommend it to my board. And I know if my board had known those precise figures, they would have been, I think, disinclined to go along.

We made a very concerted effort to make sure that there was a communication to all of those individuals affected, and you can identify them ahead of time, that that communication went in redundancy both to the patient and to the prescribing physician. And that's the only way to do it.

So I think that having some rules that require

that there be a communication to both parties affected and that there even be, I think the appropriate way would be a three-month transitional period in which I am held harmless if I still use my old drug instead of the one that it's been changed to. And during that period of time I get a warning and then after three months...

We did that and we were able to move about 40,000-some of those 52,000 folks to a new drug benefit. We forego a great deal of the savings by having allowed a lengthy -- we did a six-month transitional period in order to minimize the outcry and a heck of an educational job. But when all was said and done we got good buy-in and ultimately ended up saving about $9 million a year.

DR. REISCHAUER: A couple of observations. One is you mentioned in the presentation, but I don't think it was in the written material, the beneficiary perspective with respect to formularies which is what counts towards your movement up the progression of basic coverage, doughnut hole, catastrophic. And in most plans that doesn't make any difference because you're in the same system throughout. But in this peculiar benefit that we've designed, it's terribly important.

And remind me whether if you have a tiered system and you choose a high tier copayment whether the copayment above the first tier counts towards your spending? I don't think it does.

MS. BOCCUTI: If it's a covered drug then your cost-sharing counts. But if you try to get it moved up to -- well, your cost-sharing counts, am I correct, Joan? current job.

DR. SOKOLOVSKY: There's nothing in the law as I read it that would say that if you purchased a drug at a higher tier, if it was on the formulary, that it wouldn't count as part of your out-of-pocket spending, as opposed to a drug that was not on the formulary.

MS. BOCCUTI: It's non-formulary drugs.

DR. REISCHAUER: Non-formulary drugs don't count.

DR. NEWHOUSE: I have a question. As I read the law, this was the default cost-sharing. And that if you used a formulary, you just paid X dollars per scrip, as happens in the commercial world. It's not that you've progressed on into a doughnut.

DR. REISCHAUER: Go through that again.

DR. NEWHOUSE: Maybe I misunderstood your question but I thought your question was are the copayments going to be in effect be reimbursed by some other policy that has this $250 deductible followed by 75 percent reimbursement and so forth and so on? Is that what you're asking?

DR. REISCHAUER: If you had a standard benefit and you were bring reimbursed for 75 percent, 25 percent for formulary drugs would go into your out-of-pocket number which would sort of make you eligible for catastrophic,

eventually. If you bought non-formulary drugs the total spending -- you wouldn't would get reimbursed for anything and none of the money would push you up towards the catastrophic eligibility.

DR. NEWHOUSE: You may be right but that wasn't how I read the law.

MS. BOCCUTI: It's our understanding that that's what's written in the law, that if you purchase a non-formulary drug it does not count towards your personal out-of-pocket spending. It's called incurred spending and it's not an incurred spending.

But if you do get a non-formulary exception, then that's a different story. Then it's as if it were a covered drug.

DR. NEWHOUSE: Ah, but that's if the plan is using this cost-sharing structure of $250 deductible, et cetera. But suppose instead they're using $20 per month copays? Then what? And $50 if you're off formulary?

DR. SOKOLOVSKY: If you were using that structure, the $20 would count. But the $50, if it was off formulary would not count towards your out-of-pocket limit. I think there are a lot of things about the law that will be revealed in regulation.

DR. REISCHAUER: That's another issue which I wanted to bring up which is you've gone through a series of things that are not required by the law. But some of them could be in the regulations, I think. And we have a set of regs applicable to the discount drug card which, in some respects, are more stringent than the implications of what could happen under the basic benefit.

And I thought some description of how these are handled in the regs for the discount drug card, because I would think it's going to be hard to back off of some of those. They have to put their formularies on a computer accessible form where you can go in and see what it is and calculate what your drugs are. That's not precluded as being, I think, part of the regs that the Secretary could issue on the basic card. And I think it would be hard to take a step back from that level.

MS. BOCCUTI: There's two issues that I would bring up about the drug discount card which is set to begin in June 2004 and it runs until the beginning of the drug benefit. So it runs to the end of 2005.

About your first comment on the posting say of the drugs that the sponsor determines to be giving the discount. I think they do have to list that. That is not the case for the Medicare drug benefit.

Keep in mind that there is a distinction between the drug discount card program and the Medicare drug benefit in that the drug discount card program has a classification system and that is not really the formulary. Think of it a little bit differently than a formulary.

And what the sponsors are going to be offering is a discount of at least one drug within each therapeutic category. That's what's required. But the therapeutic categories have been predetermined.

I can talk a little bit more about that if you want but I want to feel it out here and see.

DR. REISCHAUER: No, I was just thinking of including some description of that in this discussion.

The third point that I wanted to bring up was the discussion of comparative drug study effectiveness. It's sort of almost a footnote at the end of this presentation.

I think this is an issue that is sort of larger than drugs. As you point out it's how do we evaluate the effectiveness, the cost-effectiveness of medical interventions of all kinds? And our lack of current knowledge and the need for some kind of institutional reform that would devote more resources to this and provide what is basically a public good for the world more broadly rather than have Aetna do its little studies and Kaiser do its studies.

I think, I would hope that whatever we say here doesn't preclude the possibility that we would get into this in a much more serious way with sort of an overall kind of study. So that's just a plea.

DR. MILLER: There have been internal conversations on this and I think what we would be like to do is when we bring it back is talk about a broad range of ways these things could be dealt with because you could think of public and private partnerships and that type of stuff. This has been discussed inside, We just didn't think that this was quite the --

DR. REISCHAUER: Finally, I need some education. What actually is U.S. Pharmacopeia? Is it non-profit? is it for-profit? Is it a membership organization?

MS. BOCCUTI: It's a non-governmental organization that works -- their mission is on quality of prescription drugs and they set standards.

DR. REISCHAUER: But General Motors is a non-governmental organization.

DR. ROWE: [off microphone.] Only recently. It used to be a governmental agency.

MS. BOCCUTI: It's non-profit and they publish books that pharmacists and other --

DR. REISCHAUER: Who funds it?

MS. BOCCUTI: They fund themselves through the publication of this book which is a resource because it's like recipes. It tells you what the requirements and the standards are for the drugs.

MR. DeBUSK: It's an encyclopedia of drugs.

MS. BOCCUTI: You could say that.

MR. DeBUSK: It's been around for years.

DR. REISCHAUER: What gives it its authority?

DR. ROWE: It's authoritative.

DR. NELSON: It's like Good Housekeeping seal of approval, Bob. Bob, for vitamins and things of that sort, if they meet USP standards they state that. So they have production standards and so forth that don't apply as much to the prescription drugs, although their compendium covers anything. But if you buy a USP vitamin, for example, you're assured that they met certain standards in production.

MR. SMITH: Is the drug industry equivalent of the Underwriting Laboratories for the insurance company.

DR. ROWE: But they don't test the drugs themselves.

MR. SMITH: They don't?

DR. ROWE: That's my understanding.

MS. BOCCUTI: That's correct.

MS. DePARLE: There's more than one, the blue book and the red book, right? Which one is --

MS. BOCCUTI: I don't know the color. There's more than one.

DR. ROWE: I'd like to get back to this question that Bob raised for another minute if we could. Have you heard enough about the USP, in terms of what you need to know?

DR. REISCHAUER: I believe that no one knows more than I do, so I can continue to speak on the subject.

DR. ROWE: Maybe not as authoritative as I thought.

I want just to reflect on this idea that Bob brought up, which is mentioned on the next to last page and you talked about it, about basically the evidence based, the need for evidence-based research comparing the efficacy of these drugs, which is apparently not really done is the FDA approval process of comparing one to the other. It's just whether it's safe and effective qua the drug itself.

I think it's really important for us to consider this more broadly than just drugs and there, of course, are bridging things like drugs eluding stents. Well, is that a drug or not? I guess it's a stent but it's a drug, too. So there are lots of technologies.

Health plans, and I'll try to speak from the point of view of a health plan for a minute. Health plans function best when there is evidence in the literature to permit or to guide decisions with respect to copayments, deductibles, availability, coverage, et cetera. And the BlueCross BlueShield Association has a group brought together of distinguished people like Barbara McNeil and others are on that.

And then, as Bob pointed out, each of the company's larger independent for-profit company has its own kind of mini Office of Technology Assessment, if you will, mini-OTAs, all doing redundant, sometimes conflicting analyses on what literature is available.

And every time there's a difference between one company's coverage and another company's coverage then that provides a source of irritation and justifiable complaint amongst consumers, et cetera. It goes on and on.

We don't have an OTA anymore for whatever reasons. And I think that -- I can't speak for the organization, which is now called the America's Health Insurance Plans. It used to be called AAHP HIAA but recently changed its name to AHIP. That organization, I think, strongly feels that we need some sort of full thickness assessment organization that can do meta-analyses or bring various data together to be considered in a public forum in an independent way. I think this is in everyone's best interest.

If we could, as MedPAC, find it within the scope of our agenda for Medicare beneficiaries to comment on that or think about it -- I'm not trying to add another study to an already overburdened staff -- I just think Bob is right on. We feel a critical need for this.

DR. NEWHOUSE: Two different kinds of comments. First, on the exchanges that Bob and Jack were just having I certainly think that we underinvest in this kind of research so I'm comfortable with trying to push it along. But I'm a little more tempered than this might seem at first blush. There's two different kinds of issues I have.

One is the lifetime usefulness of this research is limited if a new drug for a condition comes along that makes the old treatments obsolete. And that happens frequently enough that it would limit the amount of investment one might want to make.

And the second is a similar kinds of issue. Here I'm thinking of, in particular, cancer drugs and to some degree AIDS drugs, which are both frequently combinations of drugs.

And second, at least in the cancer case, it's frequently the case or will be going forward as we get away from the maximum tolerable dose into more targeted drugs, that the optimal dose will become uncertain or will be refined over time. This happens even now. There's been a major improvement in childhood leukemia survival with really no new agents because dosing has improved over the last couple of decades.

Then the issue becomes what combination do you test and at what dose levels and so forth? And that adds another level of uncertainty beyond that a new agent may come along and render what you did not that useful.

So I think just in the text maybe something that painted a picture about what the payoff from the research might be.

Then the second, I'd still like to go back to the question I was having with Bob earlier and Joan. As I read the law, the law said government was going to pick up 74.5 percent of the cost of the private plan and the rest would

be paid by the beneficiary in some combination of cost-sharing and premium.

Then the 74.5 percent in turn, and now I can't remember whether it was either 80 percent or 95 percent, but if you got over I think $5,100 or some such for those people the government would act like an outlier or a reinsurer and the government would pick up some high percentage of those costs. You can tell me if it's 80 or 95.

DR. SOKOLOVSKY: The government picks up 80 percent.

DR. NEWHOUSE: And then the remainder would be put into the subsidy to the premium. So the government was putting in 74.5 percent and they picked up these outlier costs and the remainder went toward a premium subsidy. And then there was this cost-sharing structure that everybody has remarked upon. And then what couldn't be made up in the cost-sharing structure from the consumer's share would go back to the premium. That was how I read the law.

But then there was a clause that said plans may use formularies. The question was how that -- this was the exchange and Bob and I had -- how that played against this cost-sharing structure if at all? Since the formularies obviously had higher cost-sharing for stuff that's off the formulary -- this could be pick up in regulation but I didn't read anything in the law that specified that the higher cost-sharing stuff would be folded into this strange deductible and doughnut and so forth structure. Was that misreading the law?

DR. SOKOLOVSKY: I think we're talking about two different issues here.

DR. NEWHOUSE: That's why I'm asking.

DR. SOKOLOVSKY: One of them is an issue that is perhaps the toughest issue out there right now and that we're not really ready to say -- we're not ready to produce research on it, but it's the issue of actuarial equivalents which is that the cost-sharing that's set up in the standard benefit plans don't have to use. They can come up with another benefit as long as it's actuarially equivalent. And there seems to be very little consensus about what that means but it means they can change -- I mean, everyone agrees they can change their cost-sharing as long as for a standard population the amount of costs that the government would pay would be approximately the same.

DR. NEWHOUSE: Exactly. So I read that to mean that as long as you were actuarially equivalent you could have $20 a month copays and $50 a month copays or whatever the copays came out to be. But then it wasn't the case that there was some other thing that was going to reimburse 75 percent of these copays for a region and then nothing and so on.

DR. SOKOLOVSKY: There is an additional piece of the law that says that if a drug is not on the formulary, as

opposed to having a different kind of cost-sharing system, if it's not on the formulary, then the beneficiary not only pays the full cost of it but it doesn't count for their out-of-pocket limit. It's not part of the government subsidy. It's not part of what the plan pays.

DR. NEWHOUSE: That's separate from the lifestyle drugs that the law specifies that are outside coverage altogether?

DR. SOKOLOVSKY: Yes.

DR. REISCHAUER: But also, while you can set up your own cost-sharing structure there are limitations. You have to have $250 deductible and you can't have spending over $5,150, right?

DR. NEWHOUSE: [off microphone.] I don't think that's right.

DR. REISCHAUER: And the catastrophic has to start at the same dollar out of pocket; is that right?

DR. SOKOLOVSKY: Yes, there are a bunch of different places, limitations, on what you can do. But it still seems to be -- Rachel and I have been going to a number of conferences where actuaries talk about these issues and the thing we've found is how little consensus there is on what can and can't be done.

DR. NELSON: I think it's important to give some attention to how disruptive changes in formularies can be for the patients and also expensive. The patient is on a stable program with a cholesterol-lowering drug, for example, and a beta-blocker and so forth. And if that's changed then they have to be monitored and make sure it doesn't negatively impact their control and that they don't get muscle pains or other side effects that they weren't having when they were on a stable, satisfactory management program before.

So whatever we can do to build stability into the formulary so it's not changing at just whims will be important from the standpoint also of saving money, I believe.

The second point is that physicians are being driven nuts by multiple formularies that they are expected to know which of 2,000 drugs are on which formularies. And to the degree that Medicare can make it easier by providing them some simple software that lets them know if a Medicare patient is prescribed a certain drug whether it's covered are not and that provides updates, that is updated periodically, I think not only just for reducing the hassle but also to assure that physicians don't have another incentive to just say to hell with the Medicare patient anyway. It's important then from the standpoint of access, in my mind.

MS. BOCCUTI: I mentioned that the presentation yesterday got into a little bit of some incentives in the law regarding e-prescribing that may -- this is something

very much in its infancy and is just starting in some places and some places are finding it to work well and others not at all. So that's something that could be an offshoot of what you've brought up. And we'll touch on that a little in the chapter.

MR. HACKBARTH: Okay, thank you very much.